Basic Building Block Profile

Building Block: Operation and Coordination

Vision

Operation & Coordination BBB requires a clinical and operational platform that provides critical, real-time oversight dashboards throughout the conduct of the Pilot Study and is compliant with EU/ECC Global Data Protection Regulation (GDPR) requirements as well as local regulations and laws. Oversight dashboards would be access controlled such that only study monitors, study/site auditors, EMA inspectors, and select clinical study team (CST) members would have an instantaneous, real-time overview of clinical site performance and study operations. Oversight dashboards would be positioned to support study conduct, internal audits to promote inspection readiness, and EMA inspector visits.

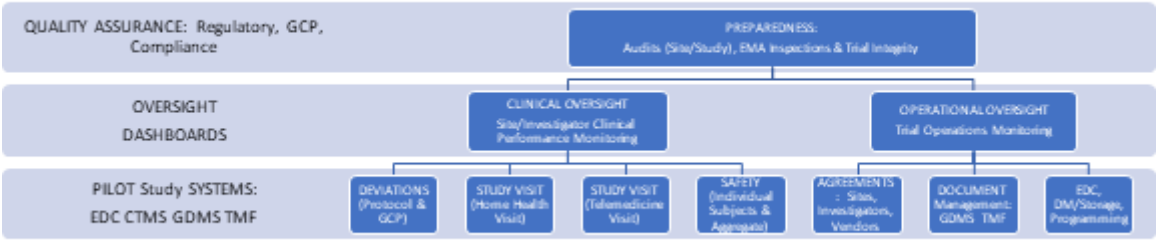
Activities

Functional Requirements

Operation & Coordination BBB activities encompass the following functions:

Technical Requirements

Operation & Coordination BBB



Functional requirements and Technical requirements

Systems must be configured to accommodate multiple, simultaneous end-users' access requirements (e.g. 2-factor authentication), and comply with protocol specified data/records protection and retention. System training, business continuity planning, user acceptance testing, automated functionality (e.g. auto-save; auto-log-off for idle periods), and tech support ("help desk") will be prerequisites.

To ensure participant data privacy, access-control systems for the integrated platform will only permit identity-authenticated end-users to access the systems and the dashboards drawing metrics from the systems complete all of the activities in the graphic above:

- clinical oversight tasks are **required** to be available prior to study start to monitor timeliness of direct data entry, timeliness of upload of electronic source documents,

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visualize compliance with completion of participant-reported and clinician-reported data, visualize wearable device(s) data, and visualize vendor-specific data; each with intact audit trails).

- study operational oversight tasks are **required** to be available prior to study start to comply with Study Monitoring Plan and complete site monitoring activities, protocol and GCP deviations identification and remediation, data management database maintenance (eCRF completion and cleaning; query issuance and time to query resolution, regulatory documents and other documents in TMF and GDMS).

Operation and coordination dashboards will be **required** to efficiently display all oversight metrics for internal auditors and EMA inspectors.

Included activities in the RFP

The following activities are included in the RFP:

OPERATIONAL OVERSIGHT

Any contracted vendor providing oversight dashboard analytics must be provided controlled access to assess study recruitment data, EDC and eSource data, source document locator completeness data, study visit scheduling data, Trial Master File (TMF) completeness data, regulatory document submission packet components in the Global Document Management System (GDMS), and any other relevant operational data as frequently as specified by the study sponsor.

CLINICAL OVERSIGHT

Any contracted vendor providing clinical oversight dashboard analytics must be provided controlled access to assess protocol and GCP compliance data, study visit scheduling and completion data, data entry timeliness and completeness data, query issuance and resolution data, and regularly scheduled safety data updates (timestamped and auditable).

TELEMEDICINE VISIT MANAGEMENT

Any contracted vendor providing telemedicine visit management must provide high quality audiovisual interactions between study participants and multiple (potentially simultaneous) investigational site personnel (e.g. investigator, study nurse, pharmacist). The vendor must provide efficient, scheduling solutions which account for participant and investigational site personnel availability. Following each telemedicine visit completed, the vendor must elicit technology satisfaction responses from all parties included in the study visit to identify and quantify satisfactory and non-satisfactory aspects of the study visit.

STUDY OVERSIGHT

Excluded activities from the RFP

The activities below are already covered by internal partner and **excluded from the RFP**:

- Performance monitoring
- Document management
- Home health visit management
- Inspection facilitation
- System approval facilitation
- Regulatory management

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- Vendor management
- Safety management
- Manage protocol and GCP deviations
- Creation of informed consent forms

RFP - Knockout Criteria

For the activities included in the RFP we have identified a number of knockout criteria that will exclude the technology vendor in the case that one or more of them are not met.

Operational Analytics:

The technology will be rejected if:

1) Not able to demonstrate operational performance oversight dashboards functionality

Study Oversight:

The technology will be rejected if:

1) Not able to demonstrate operational performance oversight dashboards functionality

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